K083449

510(k) Summary Pursuant to 21 CFR 807.92

JUN 12 2009

1. Submitted By: Pioneer Surgical Technology
375 River Park Circle
Marquette, MI 49855

2. Contact: Jon Gilbert
Pioneer Surgical Technology
375 River Park Circle
Marquette, MI 49855
(906) 226-4812

3. Product: Pioneer E-Matrix Bone Void Filler
CFR Section 880.3045 Resorbable Calcium Salt Bone Void Filler Device
Class II (special controls)
Product Code: MQV

4. Common/Trade Name: Filler, Bone Void, Calcium Compound
Pioneer E-Matrix Bone Void Filler

Description:
Pioneer E-Matrix Bone Void Filler is a gelatin-based bone void filler for use in repairing bony defects in the extremities and pelvis that are not intrinsic to the stability of the bony structure. The product is provided sterile, for single use only, and is supplied in granular form to be reconstituted at the time of use. A commercially available dispensing syringe and a mixing spatula are included in the product package.

Intended Use/Indication:
Pioneer E-Matrix Bone Void Filler is intended for bony voids or gaps that are not intrinsic to the stability of bony structure. The product is indicated to be gently packed into bony voids or gaps in the skeletal system (extremities and pelvis). These defects may be surgically created osseous defects or defects created from traumatic injury to the bone. The product provides a bone void filler that resorbs and is replaced by the growth of new bone during the healing process.

Substantial Equivalence:
Pioneer E-Matrix Bone Void Filler is comparable to Bone Void Filler devices already on the market in several characteristics which may include indications, porcine gelatin carrier, and presentation.

Devices to Which Substantial Equivalence is Claimed:

K081558 – NanOss Bone Void Filler

K032288 – Vitoss Scaffold Foam Bone Graft Material

K071187 – MicroFuse Bone Void Filler

Conclusions:
The comparisons and testing conducted on Pioneer E-Matrix Bone Void Filler demonstrate that the device is substantially equivalent to other bone void fillers currently in commercial distribution.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Pioneer Surgical Technology
% Mr. Jonathan M. Gilbert
Vice President, Regulatory & Clinical Affairs
375 River Place Circle
Marquette, Michigan 49855

JUN 12 2009

Re: K083449
Trade/Device Name: Pioneer E-Matrix Bone Void Filler
Regulation Number: 21 CFR 888.3045
Regulation Name: Resorbable calcium salt bone void filler device
Regulatory Class: II
Product Code: MQV
Dated: June 4, 2009
Received: June 9, 2009

Dear Mr. Gilbert:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/cdrh/comp/ for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/cdrh/mdr/ for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

for

Mark N. Melkerson
Director
Division of Surgical, Orthopedic,
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number: K083449

Device Name: Pioneer E-Matrix Bone Void Filler

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(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K083449

Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)